UNITED STATES DISTRICT COURT
NORTHERN DISCTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION This Document Relates To: Casey Brubaker, et al. v. Actavis, Inc., Case No. 15-cv-0426	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. Counter-Statement of Facts

In February of 2013, Plaintiff-husband Casey Brubaker ("Plaintiff-husband") went to his family care medical clinic and asked to be prescribed testosterone replacement therapy ("TRT"). Dep. Tr. Brubaker 103:3-25. He had seen disease state awareness commercials about "Low T" which referenced getting older and symptoms like fatigue and low sex drive. Id. He had gone on various websites related to "Low T"—including websites related to AndroGel and Axiron—and he had taken an online questionnaire related to the symptoms of Low T. Id. at 109:22-110:14. He told his medical provider, physician's assistant Carrington Horton ("PA Horton"), that he was having the symptoms of Low T and he wanted treatment. Id. PA Horton ordered a blood test. Id.

In November of 2013, Plaintiff-husband returned to PA Horton at the clinic after undergoing the blood test. Id. at 123:4-25. PA Horton initially prescribed Plaintiff-husband Testim. Id. at 125:18-21. PA Horton believed that the etiology of Plaintiff-husband's low testosterone level was potentially obesity, diabetes, and opioid use. Dep. Tr. PA Horton at 98:22-99:12.

Plaintiff-husband took the script to his pharmacy, but he was told that Testim was not covered by his insurance. Dep. Tr. Brubaker at 128:1-14. The pharmacist informed PA Horton, and PA Horton prescribed Androderm. Id.

PA Horton was familiar with Androderm. He had prescribed it before and had previously read the label. Dep. Tr. PA Horton at 134:2-17. PA Horton relied on the label to be accurate and describe the risk profile of Androderm. Id. at 130:23-137:7. PA Horton was unaware of the risk of myocardial infarction associated with the product in 2013. Id. at 139:25-145:1. Also, PA Horton had been exposed to TRT and Androderm detailing and advertising. Id. at 148:4-149:12.

Plaintiff-husband filled his Androderm prescription. Dep. Tr. Brubaker at 134:6-7. After receiving the prescription, Plaintiff-husband went onto the Androderm website for information about the product. Id. at 210:21-212:6. He saw no warnings related to heart attacks and no statement that the product was not approved to treat age-related declines in testosterone (hereinafter late-onset hypogonadism, or "LOH"). Id.

Plaintiff-husband used the Androderm product through March of 2014, when he suffered a heart attack.

PA Horton testified that if he had known the information contained in the 2015 Androderm label in 2013—namely, the warning related to cardiovascular risk ("MACE warning") and the limitation of use that Androderm had not been proven to be safe and effective for LOH—he would not have considered Plaintiff-husband to be a "solid candidate" for Androderm therapy, and he would have passed that information on to Plaintiff-husband so that Plaintiff-husband could make an informed decision about whether to use the product. Dep. Tr. PA Horton at 138:25-146:16.

Plaintiff-husband would not have used Androderm if he had been informed in 2013 that the product had not been proven to be safe and effective to treat men with low testosterone due to aging,

or had he known that the product carried a possible risk of heart attack or stroke. Dep. Tr. Brubaker at 211:2-22.

II. LEGAL STANDARD

It has long been held that "summary judgment is a form of relief which should be applied with caution to the end that litigants be allowed a trial on bona fide factual issues." *Int'l Ass'n of Machinists and Aerospace Workers v. J.L. Clark Co.,* 471 F.2d 694, 697 (7th Cir. 1972). All facts must be construed in the light most favorable to the non-moving party. *Estate of Perry v. Wenzel, 872 F.3d 439, 452 (7th Cir. 2017).* The movant bears the burden of showing that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. *Dunn v. Menard*, 880 F.3d 899 (7th Cir. 2018). There is a genuine issue of material fact if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Id.

III. ARGUMENT

A. Plaintiffs' have Claims Against Actavis, Inc., or Alternatively Should be Permitted to Amend their Complaint to Add the Entities Defendant Contends are Liable.

Defendant appears to argue that Actavis, Inc., "a holding company," is not the proper corporate form liable for injuries caused by Androderm. First, this is disingenuous. California law recognizes successor liability. *See Brown Bark III, L.P. v. Harver*, 219 Cal. App. 4th 809, 822 (Ct. App. Cal. 2013). As noted in the report of Dr. Peggy Pence, it is public information that Watson Pharmaceuticals, Inc., the maker of Androderm, acquired Actavis in October of 2012 and announced its adoption of Actavis, Inc., as its "new global name" on January 24, 2013. Report of Dr. Pence at p.43.

Second, this case was selected as a bellwether by Defendant. If, as it argues, Plaintiff named the incorrect corporation, then this matter would not be representative and would not further the bellwether process. Plaintiffs will amend their Complaint to include whichever corporate entities—

all of which have been on notice of this claim from their "holding company"—that Defendant asserts are liable, with the Court's permission.

B. There are Genuine Issues of Material Fact Regarding Causation, Precluding Summary Judgment.

Defendant's motions to exclude the opinions of Plaintiffs' experts should be denied for the reasons set forth in the responses to those motions.

C. **Plaintiffs' Negligence Claims Should Proceed to the Jury**.

1. **Defendant Misrepresents Plaintiffs' Negligent Design Defect Claim**.

As other TRT defendants have done previously, Defendant misrepresents the thrust of Plaintiffs' design defect claim. Plaintiffs do not claim that there was a defect in Androderm's formulation; rather, Plaintiffs contend that Androderm was dangerous because it was marketed for the wrong conditions and not accompanied by adequate warnings of the drug's risks. The Court had already denied similar motions by AbbVie and Auxilium. See CMO No. 76 at p. 28.

2. Plaintiff's Failure to Warn Claim should Proceed to Trial.

First, Defendant makes a convoluted argument that Dr. Pence failed to offer an opinion sufficient to sustain Plaintiffs' claims. This is incorrect. Dr. Pence opines that Defendant engaged in off-label marketing, that it should have been aware of off-label usage of its product, and that it should have been aware of potential cardiovascular risk associated with its products. Further, she opines that Defendant should have done the following: (1) ceased off-label promotion of its product; (2) warned that Androderm carried a potential risk of cardiovascular events and that it had not been sufficiently studied or tested for this risk; and (3) warned that Androderm was not proven to be safe or effective to treat LOH. See Report of Dr. Pence at pp. 146-48.

Second, Defendant argues that it did not have a duty to warn. It argues that the MACE warning added to the Androderm label in 2015 "reflects a determination that Androderm has not been shown to pose a MACE danger or risk." It argues that it did not have a duty to warn that its product

had not been adequately studied. It also argues that it did not have a duty to warn that its product had a limited indication and that use outside of that indication was off-label and had not been proven safe or effective. Dr. Pence disagrees with Defendant on all of these points, and she opines that the FDA would not have mandated a label change without reasonable evidence of a causal association between the risks posed by Androderm and potential harm. Id. Further, the Court has already determined that a TRT manufacturer has the duty to adequately study its products, and that such a claim is part-and-parcel of Plaintiffs' negligence claims, rather than a freestanding claim as Defendant asserts. See In re Testosterone Replacement Therapy Prod. Liab. Litigation Coordinated Pretrial Proceedings, CMO No. 47, No. 14 C 1748, 2017 WL 1836435 at *14 (N.D. Ill. May 8, 2017) ("In sum, a reasonable jury could infer that AbbVie reasonably should have known that there was a possible association between TRT drugs and increased cardiovascular risk and that it needed to perform additional safety testing."). Nothing that Defendant has argued alters that ruling.

Also, the Court has previously rejected Defendant's argument that the MACE warning advocated by Dr. Pence and mandated by the FDA in 2015, is not, in fact, a warning at all. The interpretation of this warning and the regulatory history associated therewith is clearly a disputed issue of material fact precluding summary judgment.

Third, Defendant argues that there is not evidence that it made a voluntary undertaking to educate doctors and patients about its product, and that PA Horton and Plaintiff did not rely on such undertakings. This is incorrect. PA Horton testified that he had seen Androderm marketing. Dep. Tr. PA Horton at 148:4-149:12. He had seen the product packaging also. Id. at 134:2-17. He relied on the information in these materials to be accurate and complete. Id. at 139:25-145:1. Additionally, mere days after being prescribed Androderm, Plaintiff-husband went onto Androderm's website to learn about the product. Dep. Tr. Brubaker at 210:21-212:6. He relied upon the information that Defendant voluntarily placed on the website to educate the public to his detriment.

Fourth, Defendant argues that Plaintiff cannot prove proximate causation. This is inaccurate. In so arguing, Defendant takes an overly narrow interpretation of the learned intermediary doctrine and proximate cause under California law. Under California law, all a plaintiff need prove is that the prescriber would have behaved differently if he had been appropriately warned. *Stanley v. Novartis Pharmaceuticals Corp.*, 11 F. Supp. 3d 987, 1003 (C.D. Cal. 2014). Even where the prescriber testifies that he would have prescribed the product at issue had he been appropriately warned, "changes to the treatment and prescription procedures creates a triable issue of fact on specific causation." Id.; see also Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1238-39 (9th Cir. 2017) (holding under California law that a triable issue of fact existed where the prescriber testified that it was not his usual practice to read drug labeling, but when he did read it he considered it in his decision-making process and that because his "prescribing practices evolved" there was an issue of fact for the jury).

One such different behavior a prescriber can make is to pass on the information and warnings to the patient, even if he issues a prescription, so that the patient can make an informed decision about whether to use the product. See Hill v. Novartis Pharmaceuticals Corp., No. 1:06-cv-00939, 2012 WL 6004161 at *4 (E.D. Cal. Nov. 30, 2012).

Here, PA Horton testified that he was unaware of the information added to the label in 2015, including the MACE warning and the limitation of use related to LOH, and that if he had known that information in 2013, he would have (1) not considered Plaintiff-husband to be a "solid candidate" for TRT and (2) passed the information on to Plaintiff-husband who would ultimately make the decision about whether to use Androderm. Dep. Tr. PA Horton at 138:25-146:16. Plaintiff-husband testified that he would not have used Androderm if he had known the information about the MACE risk and the limitation of use. Dep. Tr. Brubaker at 211:2-22. There is clearly a genuine issue of material fact regarding whether Plaintiff-husband would have been using Androderm in March of 2014 when he

suffered his heart attack had Defendant issued appropriate warnings, and thus there are triable issues related to proximate cause.

D. Plaintiffs' Reckless and Wantonness Claim Should Proceed to Trial.

Defendant argues that this claim should be dismissed for the same reasons it argues all other claims should be dismissed. It should be put to the jury for the same reasons the other claims should proceed.

E. Genuine Issues of Material Fact Preclude Summary Judgment on Plaintiffs' Express Warranty, Implied Warranty, Negligent Misrepresentation, and Fraud and Deceptive Practices Claims.

Defendant argues that Plaintiffs' remaining claims should also be dismissed, most of which involve Defendant's off-label marketing practices. Throughout Defendant's arguments, it misconstrues the meaning of reliance. The Court has already held that reliance on Defendant's statements need not be the sole or even the predominant influence. See In re Testosterone Therapy Products Liability Litigation Coordinated Pretrial Proceedings, CMO No. 48, No. 14 C 1748, 2017 WL 1836443 at *8 (N.D. Ill. May 8, 2017). Rather, reliance on the Defendant's statements need only be a substantial factor in influencing Plaintiff-husband and his prescriber's decisions. Id.

Regarding Plaintiffs' express and implied warranty claims, PA Horton testified that he was familiar with TRT advertising and remembered seeing promotional messaging regarding Androderm. Dep. Tr. PA Horton at 148:4-149:12. He also relied on the Androderm label. PA Horton relied on information coming from the manufacturer to be accurate and complete. Id. at 139:25-145:1.

There is a genuine issue of material fact regarding whether PA Horton relied upon information and representations from Actavis about Androderm in prescribing the product. Defendant makes a baseless argument that PA Horton needed to have relied solely on statements from Actavis when initially prescribing Plaintiff-husband TRT. This is incorrect. Although PA Horton initially prescribed Testim, he had to issue a second prescription for Androderm. In writing that prescription for Androderm, PA Horton relied upon the information from Actavis—including its promotional

material and labeling—for the proposition that it was a safe and effective drug for a patient like Casey Brubaker.

Further, contrary to Defendant's assertion, there is evidence that PA Horton prescribed Androderm for LOH or age-related symptoms. He testified that he believed the etiology of Plaintiff-husband's low testosterone to be obesity, diabetes, and opioid use. Id. at 98:22-99:12. These are non-classical forms of hypogonadism, and they are exactly the off-label uses that Defendant was promoting the Androderm product to treat. This is exactly the non-classical form of hypogonadism that the FDA warned against using TRT to treat when it mandated the limitation of use in 2015.

Defendant argues that it must have had "reason to know" that PA Horton was relying upon it to furnish a product for a particular purpose. In this case, that purpose would be the treatment of LOH or non-classical forms of hypogonadism. Actavis did have such reason to know. Dr. Pence opines that Defendant had ample notice that its product was being used off-label to treat non-classical forms of hypogonadism, and that it did nothing in response, including being told by the FDA. See Report of Dr. Pence at p. 147.

PA Horton, as previously noted, relied on the information in the label to be accurate and not misleading. He also testified about seeing TRT advertising promoting use for relief of the symptoms of aging. See Dep. Tr. PA Horton at 147:9-17. Actavis, due to its co-promotion agreement related to AndroGel among other reasons, was well aware of the promoted uses for TRT in the marketplace. Despite all this notice, Actavis did nothing to inform health care providers like PA Horton that their use of the product was not within the approved indication, and they in fact promoted off-label uses of the product.

Finally, regarding Defendant's argument that Plaintiffs have not presented evidence that Androderm was not fit for the purpose that it was promoted, the limitation of use added to the label in 2015 and Dr. Pence's opinions that Androderm had never been approved to treat LOH are

sufficient evidence to raise a genuine issue of material fact as to the warranty claims. There is ample evidence, with numerous examples provided by Dr. Pence, that Defendant promoted its product off-label. This off-label promotion informed users about the intended use of the product and was a representation that it was fit for use in the context of LOH, which it was not.

Similarly, Defendant's attacks on Plaintiffs' negligent misrepresentation and fraud claims are misplaced. As before, Defendant argues that PA Horton need to have relied on statements from Actavis in prescribing Testim. This is not so. He relied on statements from Actavis in prescribing Androderm. He issued a separate prescription and used his judgment to do so. He testified that he relied on the promotional material and labeling of Androderm to be accurate

F. Plaintiff's Request for Punitive Damages are Not Barred

Consistent with this Court's prior orders, and considering the true conflict-of-laws as to punitive damages in the instant case, the choice-of-law rules of Plaintiff's home state, Minnesota, must be applied to determine which laws govern Plaintiff's request for punitive damages. Under Minnesota's analysis, it's interest in protecting its residents from wrongdoing dictates the application of Minnesota's punitive damages law.

1. The Present Conflict-of-Laws Requires a Choice-of-Law Analysis

The Parties in the instant case are domiciled, do business in, or otherwise engage in significant conduct relevant to the claims in this case in multiple states. Potentially applicable states include: California as the Plaintiff's home state and the place of injury; and Utah, New Jersey or Illinois as centers of decision-making as to Androderm. A choice-of-law analysis must be performed here because a true conflict exists regarding the availability of punitive damages under the respective state laws. Healey v. I-Flow, LLC, 853 F. Supp. 2d 868, 871 (D. Minn. 2012).

Like California, Illinois allows punitive damages, so long as the tort "is committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard for the rights of others." Parker v. Four Seasons

Hotel, Ltd., 845 F. 3d 807, 812 (2017). In contrast, New Jersey's punitive damages statute precludes punitive damages except "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question." N.J. Stat. § 2A:58C-5. Utah Code Ann. § 78B-8-201 similarly bases the recovery of punitive damages upon a showing of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference towards, and a disregard of, the rights of others. Despite negative precedent, the state of the law has sufficiently evolved to warrant re-examination of that preemption. Because the availability of punitive damages and the applicable evidentiary standards vary among these states, a true conflict-of-law exists and an adequate choice-of-law analysis is required.

2. The Choice-of-Law Rules of Plaintiff's Home State Must be Applied

Consistent with Seventh Circuit Precedent and this Court's Case Management Order 12 and Case Management Order 47, the choice-of-law rules of Plaintiff's home state, Minnesota, are the applicable rules for the analysis required here. In CMO No. 74 (Ruling on Abbvie's motion for summary judgment on failure-to warn claims), this Court stated that "[t]he Seventh Circuit has indicated that in 'foreign cases filed directly in a district court as part of ongoing multidistrict litigation,' courts generally should treat the cases, for the purposes of applicable choice of law rules, as originating outside the district and thus should apply the choice of law rules of the originating states." Case Mgmt. Order No. 47 at 50 (citing Dobbs v. DePuy Orthopedics, Inc., 842 F.3d 1045, 1049 (7th Cir. 2016). This Court clarified that "this rule applies only to foreign cases that were directly filed in the district overseeing the MDL" and that "[a]s established by the Court in Case Management Order No. 12, any actions filed in this MDL proceeding after October 24, 2014 solely against Abbvie are treated as originally filed in this district." Id.

In CMO No. 12, this Court defined which cases in this MDL will be treated as a "foreign case," that is, treated as originating in the Plaintiff's home state. It provides that any cases directly filed after the entry of CMO No. 12 "other than certain cases involving Abbvie/Abbott only…shall be

treated as if originally filed in the federal district where the Plaintiff was a citizen at the time of the filing of his or her first complaint." Dkt. No. 440 Case Mgmt. Order No. 12 at B(ii) (emphasis added). Accordingly, Plaintiff's case is a "foreign case" originating in California, as it was directly filed after October 24, 2014 while Plaintiff was a citizen of California.

3. Under Minnesota's Choice-of-Law Rules, Minnesota Law Governs Punitive Damages

Consistent with Ninth Circuit precedent, when "two states are potentially interested in having their laws applied," a governmental interest analysis is conducted by California courts. Hill v. Novartis Pharmaceutical Corp., No. 1:06-cv-00939, 2012 WL 967577, at *1 (E.D. Cal. March 21, 2012) (citing Smith v. Cimmet, 199 Cal. App.4th 1381, 1495 (2011). If the applicable rules of the competing states are in conflict, and if both states have an interest in applying its own law to the issue, California courts conduct a "comparative impairment analysis" to determine "which jurisdiction has a greater interest in the application of its own law to the issue . . ." Id. Thus, courts in California "must apply the law of the jurisdiction whose interest would be more significantly impaired if its law were not applied." Id. (internal citations omitted).

Hill v. Novartis is directly on point. In Hill, a California plaintiff sued a New Jersey defendant for strict products liability and negligence stemming from the use of Zometa (a pharmaceutical drug). Id. Defendant moved the court to apply New Jersey punitive damages law in lieu of California law. Id. After exhaustive inquiry into the choice-of-law and comparative impairment analysis standards as applied in California, the court denied defendants' motion—thus applying California's punitive damages law. See generally id. at *1-*7.

First, the court determined that the applicable laws of California and New Jersey regarding punitive damages differs materially. Id. at *2. Punitive damages are available in California products liability actions "where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice[.]" Id. (citing Cal. Civ. Code, § 3294, subd. (a)). Punitive damages are

not limited in California products liability actions, though "they are nonetheless subject to the Due Process Clause of the Fourteenth Amendment[.]" Id. (internal citations omitted). Additionally, the award must be sufficient to "deter future misconduct by the defendant" without being "so disproportionate to the defendant's ability to pay that the award is excessive[.]" Hill, 2012 WL 967577, at *2 (citing Adams v. Murakami, 54 Cal. 3d 105, 110-12 (1991).

This differs significantly from New Jersey's limits on punitive damages. See id. at *2 (noting punitive damages limitations are the greater of five times the liability for compensatory damages or $350,000). Additionally, and absent one minor exception, the New Jersey Products Liability Act prohibits punitive damages where "a drug . . . which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration [FDA] . . . and was approved or licensed[.]" Id. (citing N.J. Stat. Ann. § 2A:58C-5, subd. (c). Thus, applying New Jersey punitive damages law would interject inconsistent limitations with those contemplated under California law. Hill, 2012 WL 967577, at *2.

The Hill court next determined the interests each jurisdiction has in applying its own law. Id. at *3. At the outset, the court noted: "California's punitive damages law advances the state's legitimate interests in punishing and deterring conduct harmful to its residents." Id. (citing Simon v. San Paolo U.S. Holding Co., Inc., 35 Cal. 4th 1159, 1185 (2005). Conversely, "New Jersey places less emphasis on the deterrence aspect." Hill, 2012 WL 967577, at *3 (citing Tarr v. Bob Ciasulli's Mack Auto Mall, Inc., 290 N.J. Super. 557, 565-69 (2007). In the simplest of terms, the court noted California has "an interest in applying its (relatively more generous) punitive damages law to punish and deter misconduct harmful to Plaintiff" as opposed to New Jersey's "interest in limiting the liability of businesses that operate within its borders." Hill, 2012 WL 967577, at *4. Thus, a true conflict exists requiring comparative impairment analysis of each forum's interest in applying their own punitive damages law.

Analysis of each forum's interesting in applying its own law involves several factors. They are: 1) consideration of "whether the policy underlying a state's law was more strongly held in the past than at present (id. at *5); 2) whether "one of the competing laws is archaic and isolated in the context of the laws of the federal unions" (id.); 3) whether the law is "infrequently enforced or interpreted even within its own jurisdiction . . . " (id.); and 4) "the maximum attainment of underlying purpose by all governmental entities." Id. The court thoroughly analyzed and determined the first three factors favor neither jurisdiction. Id. at *5-*6.

Left only with the fourth factor, the court noted the case's only connection to New Jersey was that defendant maintained its principle place of business there. Id. Conversely, mucht like the instant litigation, California is where the plaintiff's injury allegedly occurred, where plaintiff lived, and where the product was marketed, distributed, and sold. Id. Thus, absent any compelling reason by defendant as to why California law should not apply, the court relied on California's punitive damages law in lieu of New Jersey.

4. A Genuine Issue of Material Fact as to Whether Plaintiff May Recover Punitive Damages Exists so Defendants' Motion for Summary Judgment Should be Denied.

California Civil Code § 3294 allows punitive damages when (a) In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant. Cal. Civ. Code § 3294 (West).

Actavis knew Androderm had not been proven adequately safe and effective to treat age-related hypogonadism, or to relieve symptoms such as erectile dysfunction, fatigue, or depression and was not indicated for those uses. *See, e.g.,* Androderm FAQs, WLI-MDL2545-00199180; 08/11/2005 FDA Memorandum of Meeting Minutes, WLI-MDL2545-00118388; and Desai Dep. Tr. 86:17-87:18;

107:17-23 and 169:2-17 (**Exhibit 9-12**, respectively) . The FDA even explicitly told Actavis, in-person, that use of testosterone replacement for aging men with "andropause" was off-label. (**Exhibit 13,** WLI-MDL2545-00118388 at 8395).

Despite this knowledge, Actavis marketed to those conditions and sought to increase physician awareness of those symptoms to grow the TRT market of and drive prescriptions. *See, e.g.*, Armstrong Dep. Ex. 9; Armstrong Dep. Ex. 8, POA 2; Knowles Dep. Ex. 6, New Hire Presentation; and Knowles Dep. Ex. 27, Low Libido (**Exhibits 14through 17**, respectively).

Even when Actavis' own Director of Regulatory Affairs, Deepa Desai reported her concerns regarding the misbranding of Androderm to her superiors, and subsequently filed suit against the company alleging she was terminated for, among other things, opposing the misbranding of Androderm, Actavis did not change their strategy. *See* **Exhibit 18** Desai Dep. Tr. 109:9-120:24; Desai Dep Ex. 12 (**Exhibit 19**); and Desai Dep. Ex. 2 (**Exhibit 20**). As explained at length above, at all times relevant to the each of the Plaintiff's claims, Androderm failed to adequately warn the medical community about the risks in question with deliberate disregard for the safety of the men to whom it was extensively marketing its product.

As the FDA has made clear, "the benefits and safety of [using testosterone products to treat symptoms in men who have low testosterone for no apparent reason other than aging] have not been established." FDA Drug Safety Communication, March 3, 2015. Not only did the vast majority of men treated with TRT not *need* it, there was no evidence it would help them at all. Against that backdrop, Androderm's understatement of risks and over-promotion of benefits takes on a particularly insidious nature. *See Proctor*, 683 N.E.2d at 1214-15.

5. EVEN IF THE COURT WERE TO APPLY ILLINOIS CHOICE-OF-LAW RULES, THIS REQUEST FOR PUNITIVE DAMAGES SHOULD NOT BE PRECLUDED.

Even if the Court were to find that New Jersey law governs Plaintiff's request for punitive damages, punitive damages would not be precluded in the instant case. Negative precedent has been called into doubt in multiple cases. In one such case, a district court conducting a choice-of-law analysis between California and New Jersey in pharmaceutical products liability case stated that:

> In *McDarby v. Merck & Co., Inc.,* 401 N.J.Super. 10, 949 A.2d 223 (2008), the appellate Division of the New Jersey Superior Court, relying principally on *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," found the exception to be preempted by FDA regulations. *Id.* at 94. The holding of *McDarby,* however, has been called into doubt by *Wyeth v. Levine,* 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) and *Forman v. Novartis Pharmaceuticals Corp.,* 793 F.Supp.2d 598 (E.D.N.Y.2011).

Hill v. Novartis Pharm. Corp., No. 1:06-CV-00939-AWI, 2012 WL 967577, at *2, n.2 (E.D. Cal. Mar. 21, 2012). Other cases giving a restrictive reading to *Buckman* after *Wyeth* include *Sullivan v. Novartis pharm. Corp.*, 602F. Supp. 2d 521 (D.N.J. 2009); Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010); Stengel v. Medtronic, Inc., 704 F.3d 1224, 1232-33 (9th Cir. 2013); and Arters v. Sandoz Inc., 921 F. Supp. 2d 813, 819-820 (S.D. Ohio 2013).

Furthermore, in *Sullivan*, Plaintiff would be presenting evidence of withheld or misrepresented information to meet the threshold for punitive damages, not in pursuit of a claim that Actavis committed fraud-on-the-FDA. As a result, Plaintiff would not be pursuing a preempted claim and his request for punitive damages should not be precluded.

G. There is Ample Evidence that Androderm Caused Plaintiff-husband's Heart Attack to Present a Triable Issue to the Jury.

Defendant's final argument relates to causation and is purely factual and disputed. Dr. Ardehali opines that Androderm caused Plaintiff-husband's heart attack. There is sufficient evidence for a genuine issue of material fact to be put to the jury. Defendant relies on its own expert's opinions, as if they were undisputed. Further, Plaintiffs will seek preclusion of Dr. Corser's inflammatory opinions in future motion practice.

H. Plaintiff-wife's Loss of Consortium Claim Remains Intact.

Because Defendant's motion as to Plaintiff-husband's claims should be denied, so too should their motion as to Plaintiff-wife's derivative loss of consortium claim.

I. Conclusion

For the above reasons, Plaintiffs respectfully request that the Court deny Defendant's Motion for Summary Judgment.

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CERTIFICATE OF SERVICE

I hereby certify that on _____, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

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